510(k) Summary

MAY 30 2008

Contact: John Sanders
Scient'x USA Inc.
1015 Maitland Center Commons
Suite 106 A
Maitland, Florida 32751
407.571.2550

Device Trade Name: Tribeca™ Cage

Manufacturer: Scient'x USA Inc.
1015 Maitland Center Commons
Suite 106 A
Maitland, Florida 32751

Common Name: Intervertebral body fusion device

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX

Indications For Use:
The Scient'x Tribeca™ Cage implants are indicated for use with autogenous bone graft as an intervertebral body fusion device at either one or two contiguous levels in the lumbosacral spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Tribeca™ Cage is to be used in skeletally mature patients who have had six months of non-operative care.

The Tribeca™ Cage is implanted using an anterior or posterior approach and is intended to be used single or in pairs with ISOBAR ø6.2mm Hemispherical Screws with Offset Clamps and ø5.5mm Rods.

Device Description:
The Tribeca™ Cage involves lumbar component spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Tribeca™ Cage is manufactured from PEEK-OPTIMA polymer and is provided non-sterile.

Predicate Device(s):
The Tribeca™ Cage was shown to be substantially equivalent to the Abbott Spine Ardis Spacer (K073202).

Performance Standards:
Testing performed per ASTM F2077 and F2267 indicates the Tribeca Cage is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scient' X USA, Incorporated
% Mr. John Sanders
Quality Assurance Regulatory Affairs Manager
1015 Maitland Center Commons, Suite, 106A
Maitland, Florida 32751

MAY 30 2008

Re: K080588
Trade/Device Name: Scient' X Tribeca™ Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: March 10, 2008
Received: March 11, 2008

Dear Mr. Sanders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080588

Device Name: Scient'x Tribeca™ Cage

The Scient'x Tribeca™ Cage implants are indicated for use with autogenous bone graft as an intervertebral body fusion device at either one or two contiguous levels in the lumbosacral spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Tribeca™ Cage is to be used in skeletally mature patients who have had six months of non-operative care.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080588